DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Kaletra
Docket No.: 01E-0089

. SEP 6 2001

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,886,036, filed by Abbott Laboratories, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Kaletra, the human drug product claimed by the patent.

The total length of the regulatory review period for Kaletra is 1,397 days. Of this time, 1,290 days occurred during the testing phase and 107 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 20, 1996.

   The applicant claims November 18, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 20, 1996, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 1, 2000.

   FDA has verified the applicant's claim that the new drug application (NDA) for Kaletra (NDA 21-226) was initially submitted on June 1, 2000.

3. The date the application was approved: September 15, 2000.

   FDA has verified the applicant's claim that NDA 21-226 was approved on September 15, 2000.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Steven F. Weinstock
Abbott Laboratories, Inc.
D377/AP6D-2
100 Abbott Park Road
Abbott Park, IL 60024-6050